

製品変更通知

2017 年 8 月 28 日

通知 ID : CN-170802

通知タイプ : 製品ラベル変更

お客様各位

Mesa のカタログ番号の分析証明書に加えられる変更についてお知らせいたします。

製品番号 :

- 77-05-CI-SSW MESA ProChem SSW
- 77-05-CI-SINT MESA ProChem SSI

直ちにこれらの製品の分析証明書は下記の様に変更されます。

- オマハ施設を廃止したことを反映するために住所が変更され、モンタナ州のボーズマンの新しい施設で製品の試験と流通が行われます。
- 製品番号と改訂番号がフッターに追加されました。
- ご使用方法是、当社の製品ラベルに完全なご使用方法を含めるように拡大されています。
- 規格適合は承認された手順に合わせて改訂されました。
- 書式設定は他のサイトの文書の書式設定に合わせてコンテンツの変更とはみなされずに変更を行います。

改訂された証明書の例を添付します。

ご不明点がございましたら MesaLabs 社の担当者にご連絡ください。



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: MESA ProChem SSW Integrator
Catalog No.: 77-05-CI-SSW
Lot Number:
Expiration Date:
Product Description: Mesa ProChem SSW is a single-use Type 5 integrating indicator.
Indications for Use: The integrating indicator is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:

- 250°F/121°C, 30 minutes Gravity
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles (IUSS):

- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 3 minutes Gravity
- 270°F/132°C, 10 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 3 minutes Gravity
- 275°F/135°C, 10 minutes Gravity

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 5 process indicators.

Certified by:

Quality Representative

Date



CERTIFICATE OF CONFORMANCE

Mesa Laboratories, Inc.
625 Zoot Way, Bozeman, MT 59718
Phone: (303) 987-8000 www.mesalabs.com

Product Name: MESA ProChem SSI
Catalog No.: 77-05-CI-SINT
Lot Number: 12-2019
Expiration Date: 12-2019
Product Description: Mesa ProChem SSI strips are designed for utilization in steam sterilization cycles operating at 132C – 135C (270F-276F) for 3 minutes or longer.
Indications for Use: When used as directed, the ProChem SSI gives visual indication that sterilizing conditions were met at point of placement. During steam sterilization, the indicator at the end of the strip changes from white to black.

This certificate is issued to confirm that the product listed above has been tested by Mesa Labs and satisfies performance requirements after exposure to saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Type 4 process indicators.

Certified by:

Quality Representative

Date